K113017

PULPDENT CORPORATION

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MAR - 2 2012

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA

Kenneth J. Berk
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DEVICE:
Trade Name: ***Pulpdent Spee-Dee™ Patch***
Classification Name: Tooth shade resin material
FDA Product Code: 76 EBF, 21 CFR Part 872.3690

PREDICATE DEVICES:

Pulpdent *Embrace™Dual Cure Composite Materials*

Pulpdent *Embrace™ Pit and Fissure Sealant*

Kuraray *Clearfil™ Photo Core*

DESCRIPTION AND INTENDED USE:

Spee-Dee Patch is a visible light cured, glass-filled resin that is intended as a vital tooth build-up material where restorations were removed and must be built up for crown preparation; as a non-vital tooth post and core; as a build up material; and as a repair material to repair fractured cusps, lost partial or whole fillings, chipped crowns, broken teeth, crowns, or bridges.

COMPARISON WITH PREDICATE PRODUCTS:

Spee-Dee Patch is substantially equivalent in design, composition, performance, intended use, safety and effectiveness to the predicate products listed above. *Spee-Dee Patch* contains the same Embrace technology and resin composition as *Embrace Pit and Fissure Sealant* and *Embrace Dual Cure Composite Materials* (marketed as Spee-Dee™ Build-Up), except that Spee-Dee has dual cure chemistry.

Pulpdent Spee-Dee Patch	Visible light-cure, resin-based, flowable material that contains no Bisphenol A.	Used to patch teeth or core preparations and as a core build-up material.	Embrace Monomer Mix Photo-initiator Filler: Barium glass and submicron silica
Pulpdent Spee-Dee Build-Up Material K 071278	Dual-cure, resin-based material that contains no Bisphenol A.	Build-up and repair material.	Embrace Monomer Mix Photo-initiator Chemical initiator Filler: Barium glass and submicron silica
Pulpdent Embrace™ Pit & Fissure Sealant K 020287	Hydrophilic, visible light-cure, resin-based material that contains no Bisphenol A.	Seals the pits and fissures in teeth.	Embrace Monomer Mix Photo-initiator Filler: Barium glass and submicron silica
Kuraray *Clearfil™ Photo Core* K882006	Light cured, resin-based composite.	Build-up and repair material	Monomer Mix Photo-initiator Filler

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Summary of Performance Testing – Bench

The following test results demonstrate that *Spee-Dee Patch* performs as intended:

Light Cure Setting Time	< 20 seconds
Working time in ambient light	> 5 minutes
Clinical depth of cure	> 4 mm
Compressive Strength	45,240 ± 3480 p.s.i. / 312.0 ± 24.0 MPa
Specific gravity	1.520
Flexural Strength	13,775 ± 1450 p.s.i. / 95.0 ± 10.0 MPa
Diametral Tensile Strength	7540 ± 290 p.s.i. / 52.0 ± 2.0 MPa
Shelf-life	Two years

SAFETY AND EFFECTIVENESS:

From the above comparisons, the bench testing and the ten years organizational experience with Embrace resins, it can be concluded that *Spee-Dee Patch* is substantially equivalent in design, composition, performance, intended use, safety and effectiveness to the predicate products listed above.

The predicate products have been found substantially equivalent under the 510(k) Premarket Notification process as Class II Dental Devices under CFR 872.3690, 872.3275 and 872.3765 and have been on the market for years with no reports of safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Kenneth J. Berk
Director of Research
Pulpdent Corporation
80 Oakland Street
Watertown, MA 02472

MAR - 2 2012

Re: K113617
Trade/Device Name: Spee-Dee™ Patch
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Codes: EBF
Dated: December 1, 2011
Received: December 7, 2011

Dear Mr. Berk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510 (k) Number: **K113617**

Device Name: ***PULPDENT SPEE-DEE™ PATCH***

Indications for Use:

Spee-Dee Patch is a visible light cured, glass-filled resin that is intended as a vital tooth build-up material where restorations were removed and must be built up for crown preparation; as a non-vital tooth post and core; as a build up material; and as a repair material to repair fractured cusps, lost partial or whole fillings, chipped crowns, broken teeth, crowns, or bridges.

Prescription Use __X__ or Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) *(21 CFR 807 Subpart C)*

Please do not write below this line. Continue on another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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